



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re the application of: Winfried Edelmann *et al.*

Serial No.: RCE of 09/658,734

Filed: September 11, 2000

For: METHODS FOR IDENTIFYING
COMPOUNDS WHICH MODULATE THE
ACTIVITY OF MSH5

Attorney Docket No.: AHN-001DV1RCE

Group Art Unit: 1651

Examiner: Davis, Ruth A.

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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DECLARATION UNDER 37 C.F.R. 1.131 BY

DR. WINFRIED EDELMANN

Sir:

I, Dr. Winfried Edelmann declare:

1. I am an inventor of the subject matter described and claimed in the above-referenced patent application.

2. I attest that I have reviewed the presently pending claims of the above-identified application.

3. I understand that the Examiner's position in rejecting presently pending claims 31 and 32 is that claims 31 and 32 are obvious in view of Winand, *et al.* (1998) *Genomics* 53:69-80) and U.S. Patent No. 6,333,153. The Examiner is relying on U.S. Patent No. 6,333,153 as teaching "a method for determining if a composition (test compound) affects (or modulates) expression of a gene encoding a MutS homolog (MSH) (col. 9 line 10-15) wherein the MutS homolog may be MSH5 (col. 4 line 35-40). The method comprises administering the test composition (or compound) to a cell containing the MutS homolog (or MSH5) and a cell which does not contain the MutS homolog followed by observing phenotypic effects on the cells to determine if the compound effects (or modulates) MutS homolog activity (col. 9 line 29-45)." The Examiner is relying on Winand *et al.* as teaching that "MSH5 is required in normal meiotic crossing over (abstract and page 69, right column) and encodes proteins which function in meiotic cells (page 69, right column)." Winand *et al.* was published on October 1, 1998, as evidenced by the attached printout from the Science Direct website which indicates a date of October 1, 1998 for the volume 53, Issue 1 of *Genomics* in which the Winand *et al.* reference appeared.

4. I attest that prior to October 1, 1998, the invention described and claimed in rejected claims 31 and 32 was completed in this country as evidenced by the following manuscript entitled "Mammalian MutS Homolog 5 is Required for Chromosome Pairing in Meiosis," (attached as Appendix A and referred to herein as "the manuscript"). The manuscript was received by the journal *Nature Genetics* on August 15, 1998, as

evidenced by the published article based on this manuscript (attached as Appendix B). The published article indicates August 15, 1998 as the date of submission at page 127, second column.

5. The manuscript describes experiments which are the basis for the above-identified patent application. Thus, the manuscript attached as Appendix A and the publication attached as Appendix B demonstrate that the experiments described in the above-identified application were completed prior to October 1, 1998 and that the discovery that MSH5 plays a role in meiosis was made prior to October 1, 1998. Based on the observation that mice carrying a null mutation in the MSH5 gene and the identification of the role of MSH5 in meiosis, the inventors conceived of the usefulness of MSH5 in assays for identifying a candidate compound useful for modulating meiosis, as is presently claimed. Thus, conception of the invention described and claimed in rejected claims 31 and 32 was completed in this country prior to October 1, 1998.

I have been warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful and false statements may jeopardize the validity of the subject application or any patent resulting therefrom, and declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true.

Date: _____

Signed: _____

Winfried Edelmann